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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/726,400

12/03/2003

Kenneth A. Jones

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EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/26/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/726,400	Applicant(s) JONES ET AL.	
	Examiner Leslie R. Deak	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
 4a) Of the above claim(s) 1-6, 12-17 and 27-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-11 and 18-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 February 2007 has been entered.

Election/Restrictions

2. Applicant's election with traverse of the originally examined claims, claims 7-11, 18-26 in the reply filed on 27 February 2007 is acknowledged. The traversal is on the ground(s) that examination on all the pending claims would not impose an undue burden on the examiner. This is not found persuasive because the newly filed claims are directed to a method that does not encompass all the limitations of the claimed device, rendering it a broader recitation of a method that does not require the use of the claimed device. Since applicant has received an action on the merits for the originally presented invention, examiner is restricting the application to address the originally filed invention.

The requirement is still deemed proper and is therefore made FINAL.

Response to Amendment

3. The amendment filed 27 February 2007 overcomes the new matter objection presented in the Final Office Action of 28 August 2007. Accordingly, the objection and corresponding claim rejections have been withdrawn.

Claim Objections

4. Claim 9 is objected to because of the following informalities: Applicant claims "the valve" in line 9. Since two valves have been recited in the parent claim, it is unclear to which valve the claim limitation refers. Appropriate correction is required.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 7-11, 18, 19, 22, 23, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,707,356 to Paul in view of US 6,315,752 to DiMatteo.

In the specification and figures, Paul discloses the apparatus as claimed by applicant. With regard to claims 7, 10, and 26, Paul discloses a pressure relief valve that is designed for use during heart surgery in an extracorporeal circuit (see column 2, lines 8-46). The valve 10 comprises a body 12 with a first inlet 14 with an axis parallel to the direction of flow (see arrow in FIG 1), a second inlet 47 with an axis parallel to flow

through the inlet, and an outlet 16 with an axis parallel to flow (see FIGS 1-2, column 3, column 4, lines 16-33)). First inlet 14 comprises a one-way duckbill valve 18 that is capable of allowing fluid from a patient's body towards the outlet (see FIG 3). The second inlet 47 comprises a two-way valve 32 that comprises inlet umbrella 34 and outlet umbrella 36 that is capable of allowing fluid to pass from a source into the valve body towards the outlet in the event of a negative pressure situation and outward from the valve into the source 47 in the event of a positive pressure situation (see column 3).

Paul fails to disclose that the first and second inlet are disposed at an angle of less than 90 degrees, but does disclose that various flow axes are contemplated within the scope of the invention (see column 4, lines 40-41). However, DiMatteo discloses a bypass graft that passes blood through the lumens of tubes 200, 210. The inlet lumens at 211, 202 are disposed at an acute angle, that is less than 90 degrees, in order to reduce turbulence between the flows entering from both lumens (see FIG 2, column 4, lines 7-15). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to arrange the inlets of the Paul device to have less than 90 degrees between them as disclosed by DiMatteo in order to reduce turbulence in the flow through the main lumen, as taught by DiMatteo.

With regard to claim 8, applicant's claim language is directed to the functional use of the claimed apparatus. It has been held that device claims cover what a device is, not what a device does. See MPEP 2114. In the instant case, applicant fails to disclose any additional structural limitations that distinguish the instantly claimed invention from that suggested by the prior art. Paul discloses that the inlet 47 is an

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ambient air conduit. However, the conduit is capable of being connected to a source of fluid, such as saline, which could relieve pressure in the circuit without introducing air into the circuit, thereby meeting the limitations of the claims.

With regard to claim 9, it is unclear what valve applicant is referring to. However, Paul discloses that the status of valves 34, 36, may be visually ascertained, providing a visual indicator of flow within the valve (see column 3, lines 45-48).

With regard to claims 11 and 23, applicant claims only that the opening pressures of the valves may be modified. Paul discloses that the valve umbrellas are operable to open at particular pressures (see column 4, lines 16-34). However, it is the position of the examiner that the opening pressure of the valves may be adjusted as a part of the manufacturing process, forming the umbrella structure of a more or less resilient material in order to adjust the opening pressures of the valves. Since the valve disclosed by Paul is capable of being adjusted, or changed, to modify the opening pressures, the disclosures of the cited prior art meet the limitations of the claims.

With regard to claim 18, the valve comprises opening 47 illustrated without any covering, which corresponds to a "transparent window," as broadly interpreted by the examiner (see FIG 2).

With regard to claim 19, the indicator comprises the umbrella section 35a of valve 35 (see FIG 2), which deforms in response to pressure through valve 32, thereby indicating the presence of flow within valve 32.

With regard to claims 22 and 25, Paul discloses that the second inlet 47 is an ambient air conduit, which allows fluid, such as air, to expel into open air in the event of excess pressure within the line.

7. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,707,356 to Paul in view of US 6,315,752 to DiMatteo, further in view of US 4,747,826 to Sassano.

In the specification and figures, Paul and DiMatteo disclose the device substantially as claimed by applicant (see rejection above) with the exception of an electronic flow detector connected to a visual display. Sassano discloses a fluid flow system for rapid venous infusion that comprises tubing, valves, and means for sensing fluid flow. The device comprises fluid flow controllers 38 (which may include valves) and monitors coupled to infusion pump 14 (see column 4, lines 14-26). The flow sensors are electronic in nature and have a corresponding visual display (see column 6, lines 23-30). The system, including its sensors and controllers, allow for rapid, automated infusion to a patient that can be monitored by an operator consulting the display (see column 2, lines 16-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to couple an electronic fluid sensor with visual display, as disclosed by Sassano, with the valve suggested by the prior art in order to provide for easy fluid flow monitoring by a single operator, as taught by Sassano.

8. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,707,356 to Paul in view of US 6,315,752 to DiMatteo, further in view of US 7,033,336 to Hogendijk et al

In the specification and figures, Paul and DiMatteo disclose the device substantially as claimed by applicant (see rejection above) with the exception of providing a venous reservoir as the source of fluid for the second inlet passage. With regard to claim 22, Hogendijk discloses a catheter assembly with a first inlet 258 and a second inlet 224, and an outlet passage 213 wherein the second inlet is coupled to a venous return line (see column 7, lines 45-67, column 8 lines 1-8, FIG 6C). The second inlet is regulated by a valve 256 that opens if the negative pressure in outlet line 213 is too great, allowing for pressure relief such that high levels of suction related aspiration will not harm the patient's vessel (see column 3, lines 45-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a venous reservoir or source as disclosed by Hogendijk to the valve apparatus suggested by the prior art in order to prevent suction-related harm to the patient's vessel, as taught by Hogendijk.

Response to Arguments

9. Applicant's arguments filed 27 February 2007, with respect to the rejection(s) of the pending claims under 35 USC 102 and 103 to Raines have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon

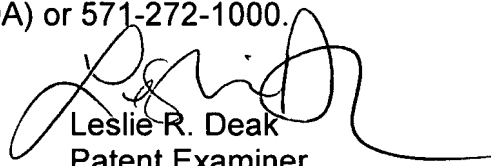
further consideration, a new ground(s) of rejection is made in view of Paul as presented above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Leslie R. Deak
Patent Examiner
Art Unit 3761
24 April 2007